



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/538,001	03/17/2006	Roberto A. Macina	DEX-0548	8198
32800	7590	12/31/2007		
LICATA & TYRRELL P.C. 66 E. MAIN STREET MARLTON, NJ 08053			EXAMINER MARTINELL, JAMES	
			ART UNIT	PAPER NUMBER
			1634	
			NOTIFICATION DATE	DELIVERY MODE
			12/31/2007	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

poreilly@licataandtyrrell.com

Office Action Summary

Application No.

10/538,001

Applicant(s)

MACINA ET AL.

Examiner

James Martinell

Art Unit

1634

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 November 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-18 is/are pending in the application.
- 4a) Of the above claim(s) 11-14 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-10 and 15-18 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 6/3/05.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

Art Unit: 1634

Applicant's election with traverse of the requirement for restriction in the reply filed on November 5, 2007 is acknowledged. The traversal is on the ground(s) that "a search of the art relating to an elected nucleic acid sequence should reveal art relating to the protein encoded thereby and antibodies thereto". This is not found persuasive because the searches of the three Groups of inventions are not co-extensive. It is noted that applicants did not argue against the selection of a single sequence for examination on the merits.

The requirement is still deemed proper and is therefore made FINAL.

Claims 11-14, 15 (insofar as it is drawn to polypeptide assays) and 16-18 (insofar as they are drawn to kits containing polypeptides (claim 16), methods of treatment using polypeptides (claim 17), and polypeptide vaccines (claim 18)) are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on November 5, 2007.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-10 and 15-18 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claims are vague, indefinite, and incomplete.

- (a) Claims 1 and 15-18 are vague and indefinite because they claim more than was elected. Claim 1 is drawn to more than one selected nucleic acid sequence. Claim 15 (parts (a)(v) and (vi) and part (b) comparing polypeptide amounts) is drawn to a non-elected invention. Claim 16 (part (e)) is drawn to kits containing polypeptides. Claim 17 (part (e)) is drawn to methods of using polypeptides. Part of claim 18 is drawn to polypeptide vaccines.

Art Unit: 1634

- (b) The recitation of "selectively hybridizes to" (claims 1, 15, and 16) is vague, indefinite, and incomplete because nucleic acid molecular hybridization is a process in which selective hybridization is dependent upon competing target in the hybridization mixture (*e.g.*, see Kennell (Progr. Nucl. Acid Res. Mol. Biol. 11: 259 (1971)) cited here as of interest). Since the claims give no information about the presence or absence of competing targets, the claims are vague, indefinite, and incomplete. The metes and bounds of the claims are not clear.
- (c) The recitation of "selectively hybridize" (claim 7) is vague, indefinite, and incomplete because nucleic acid molecular hybridization is a process in which selective hybridization is dependent upon competing target in the hybridization mixture (*e.g.*, see Kennell (Progr. Nucl. Acid Res. Mol. Biol. 11: 259 (1971)) cited here as of interest). Since the claim gives no information about the presence or absence of competing targets, the claim is vague, indefinite, and incomplete. The metes and bounds of the claim are not clear.
- (d) Claims 16, 17, and 18 are incomplete because they depend from cancelled claim 12.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-10 and 15-18 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Rosen et al (WO 00/55350 (September 21, 2000)). SEQ ID NO: 143 of Rosen et al encodes a polypeptide that is 95.3% identical to SEQ ID NO: 174 of the instant claims (see the alignment below). Rosen et al teaches uses of the polynucleotides as cancer therapeutics and cancer markers, including breast cancer

Art Unit: 1634

markers (*e.g.*, see page 375, line 6 through page 381, line 11 (use against cancers); page 346, line 19 through page 356, line 7 (uses of polynucleotides); page 330, line 6 through page 336, line 27 (therapeutic uses)); and gene therapy (page 360, line 12 through page 372, line 4)). Rosen et al also teaches the collection of nucleic acids into kits for convenience (*e.g.*, see page 349, line 15 through page 350, line 13).

Alignment of Rosen et al (WO 00/55350 SEQ ID NO: 143) with SEQ ID NO: 70

RESULT 5

AAC77749

ID AAC77749 standard; cDNA; 1235 BP.

XX

AC AAC77749;

XX

DT 08-FEB-2001 (first entry)

XX

DE Human cancer associated gene sequence SEQ ID NO:143.

XX

KW Human; cancer associated gene; cancer antigen; detection; cancer;
 KW diagnosis; cytostatic; proliferative; vulnerary; immunomodulator;
 KW antidiabetic; antiasthmatic; antirheumatic; antiarthritic; antiviral;
 KW antiinflammatory; antithyroid; antiallergic; antibacterial; cardiant;
 KW dermatological; neuroprotective; thrombolytic; coagulant; nootropic;
 KW vasotropic; antipsoriatic; antiangiogenic; gene therapy; inflammation;
 KW immune disorder; haematopoietic cell disorder; autoimmune disorder;
 KW allergic reaction; graft versus host disease; organ rejection;
 KW haemostatic; thrombolytic; cardiovascular disorder; infection;
 KW neurological disease; drug screening; ss.

XX

OS Homo sapiens.

XX

PN WO200055350-A1.

XX

PD 21-SEP-2000.

XX

PF 08-MAR-2000; 2000WO-US005882.

XX

PR 12-MAR-1999; 99US-0124270P.

XX

PA (HUMA-) HUMAN GENOME SCI INC.

XX

PI Rosen CA, Ruben SM;

XX

DR WPI; 2000-587533/55.

DR

P-PSDB; AAB43540.

XX

PT Novel isolated nucleic acids comprising sequences encoding peptides

PT

useful for treating or diagnosing *e.g.* cancer.

XX

PS Claim 1; Page 722-723; 2352pp; English.

XX

CC AAC77607 to AAC78448 encode the human cancer associated proteins given in
 CC AAB43398 to AAB44239. The proteins can have activities based on the
 CC tissues and cells the genes are expressed in. Example of activities
 CC include: cytostatic; proliferative; vulnerary; immunomodulator;
 CC antidiabetic; antiasthmatic; antirheumatic; antiarthritic;
 CC antiinflammatory; antithyroid; antiallergic; antibacterial; antiviral;
 CC dermatological; neuroprotective; cardiant; thrombolytic; coagulant;
 CC nootropic; vasotropic; antipsoriatic and antiangiogenic. The
 CC polynucleotides and polypeptides can be used for preventing, treating or

Art Unit: 1634

CC ameliorating medical conditions and diagnosing pathological conditions.
CC Polynucleotides, polypeptides, antibodies, agonists and antagonists from
CC the present invention may be used to treat immune disorders by activating
CC or inhibiting the proliferation, differentiation or mobilisation of
CC immune cells, to treat disorders of haematopoietic cells, autoimmune
CC disorders, allergic reactions, graft versus host disease and organ
CC rejection, modulate haemostatic or thrombolytic activity, modulate
CC inflammation, cancers, cardiovascular disorders, neurological disease and
CC bacterial or viral infections. The peptides, nucleotides, antibodies,
CC agonists and antagonists may be also be used in drug screens. AAC78449 to
CC AAC78457 and AAB44240 represent sequences used in the exemplification of
CC the present invention

XX

SQ Sequence 1235 BP; 257 A; 389 C; 394 G; 194 T; 0 U; 1 Other;

Alignment Scores:

Pred. No.:	6.53e-111	Length:	1235
Score:	1158.00	Matches:	221
Percent Similarity:	92.5%	Conservative:	0
Best Local Similarity:	92.5%	Mismatches:	2
Query Match:	95.3%	Indels:	18
DB:	3	Gaps:	1

US-10-538-001-174 (1-224) x AAC77749 (1-1235)

```
Qy      2 ValProGlyArgTrpArgGlnHisLeuGlnProArgArgArgCysArgSer----- 18
      |||
Db      70 GTCCAGGAAGGTGGCGTCAGCATCTGCAGCCGCGTCGACGTTGTCGGAG-CCTCCGCGG 128

Qy      19 -----LeuProThrLeuProMetGlu 25
      |||
Db     129 AGGACCCAGGAGAGCCGGACTAGGACCAGGGCCCTGGGCCTCCCCACACTCCCCATGGAG 188

Qy      26 LysLeuAlaAlaSerThrGluProGlnGlyProArgProValLeuGlyArgGluSerVal 45
      |||
Db     189 AAGCTGGCGGCCTCTACAGAGCCCAAGGGCCTCGGCCGGTCTGGGCCGTGAGAGTGTC 248

Qy      46 GlnValProAspAspGlnAspPheArgSerPheArgSerGluCysGluAlaGluValGly 65
      |||
Db     249 CAGGTGCCCCGATGACCAAGACTTTTCGAGCTTCGGTCAGAGTGTGAGGCTGAGGTGGGC 308

Qy      66 TrpAsnLeuThrTyrSerArgAlaGlyValSerValTrpValGlnAlaValGluMetAsp 85
      |||
Db     309 TGGAACTGACCTATAGCAGGGCTGGGGTGTCTGTCTGGGTGCAGGCTGTGGAGATGGAT 368

Qy      86 ArgThrLeuHisLysIleLysCysArgMetGluCysCysAspValProAlaGluThrLeu 105
      |||
Db     369 CGGACGCTGCAACAAGATCAAGTGCCGGATGGAGTGTGTGTGTGTCAGCCGAGACACTC 428

Qy     106 TyrAspValLeuHisAspIleGluTyrArgLysLysTrpAspSerAsnValIleGluThr 125
      |||
Db     429 TACGACGTCTACACGACATTGAGTACCGCAAGAAATGGGACAGCAACGTCATTGAGACT 488

Qy     126 PheAspIleAlaArgLeuThrValAsnAlaAspValGlyTyrTyrSerTrpArgCysPro 145
      |||
Db     489 TTTGACATCGCCCGCTTGACAGTCAACGCTGACGTGGGCTATTACTCCTGGAGGTGTCCC 548

Qy     146 LysProLeuLysAsnArgAspValIleThrLeuArgSerTrpLeuProMetGlyAlaAsp 165
      |||
Db     549 AAGCCCTGAAGAACCGTGATGTCTATCACCTCCGCTCCTGGCTCCCCATGGGCGCTGAT 608

Qy     166 TyrIleIleMetAsnTyrSerValLysHisProLysTyrProProArgLysAspLeuVal 185
      |||
Db     609 TACATCATTATGAATACTCAGTCAAACATCCCAAATACCCACCTCGGAAAGACTTGGTC 668

Qy     186 ArgAlaValSerIleGlnThrGlyTyrLeuIleGlnSerThrGlyProLysSerCysVal 205
      |||
Db     669 CGAGCTGTGTCCATCCAGACGGGCTACCTCATCCAGAGCACAGGGCCAAGAGCTGCGTC 728
```

Art Unit: 1634

Qy 206 IleThrTyrLeuGlyProGlyGlyProGlnArgLeuLeuThrGlnValGlyGlyGlu 224
 ||||| |||||
 Db 729 ATCACCCTACCT-GGCCAGGTGGACCCCAAAGGCTCCTTACCCAAGTGGGTGGTGAA 784

Claims 1-3, 6, 8, and 9 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by GenBank® Accession No. BE791925 (September 20, 2000). GenBank® Accession No. BE791925 encodes a polypeptide that is 95.3% identical to SEQ ID NO: 174 of the instant claims (see the alignment below). Thus, the polynucleotide of GenBank® Accession No. BE791925 is embraced by the claims.

Alignment of GenBank® Accession No. BE791925 with SEQ ID NO: 70

RESULT 1
 BE791925
 LOCUS BE791925 826 bp mRNA linear EST 20-SEP-2000
 DEFINITION 601585824F1 NIH_MGC_7 Homo sapiens cDNA clone IMAGE:3940444 5',
 mRNA sequence.
 ACCESSION BE791925
 VERSION BE791925.1 GI:10213123
 KEYWORDS EST.
 SOURCE Homo sapiens (human)
 ORGANISM Homo sapiens
 Eukaryota; Metazoa; Chordata; Craniata; Vertebrata; Euteleostomi;
 Mammalia; Eutheria; Euarchontoglires; Primates; Haplorrhini;
 Catarrhini; Hominidae; Homo.
 REFERENCE 1 (bases 1 to 826)
 AUTHORS NIH-MGC <http://mgc.nci.nih.gov/>.
 TITLE National Institutes of Health, Mammalian Gene Collection (MGC)
 JOURNAL Unpublished (1999)
 COMMENT Contact: Robert Strausberg, Ph.D.
 Email: cgapbs-r@mail.nih.gov
 Tissue Procurement: DCTD/DTP
 cDNA Library Preparation: Ling Hong/Rubin Laboratory
 cDNA Library Arrayed by: The I.M.A.G.E. Consortium (LLNL)
 DNA Sequencing by: Incyte Genomics, Inc.
 Clone distribution: MGC clone distribution information can be
 found through the I.M.A.G.E. Consortium/LLNL at: image.llnl.gov
 Plate: LLCM790 row: o column: 05
 High quality sequence start: 5
 High quality sequence stop: 787.
 FEATURES
 source Location/Qualifiers
 1..826
 /organism="Homo sapiens"
 /mol_type="mRNA"
 /db_xref="taxon:9606"
 /clone="IMAGE:3940444"
 /tissue_type="small cell carcinoma"
 /cell_line="MGC3"
 /lab_host="DH10B (phage-resistant)"
 /clone_lib="NIH_MGC_7"
 /note="Organ: lung; Vector: pOTB7; Site_1: XhoI; Site_2:
 EcoRI; cDNA made by oligo-dT priming. Directionally
 cloned into EcoRI/XhoI sites using the following 5'
 adaptor: GGACGAG(G). Size-selected >500bp for average
 insert size 1.8kb. Library constructed by Ling Hong in
 the laboratory of Gerald M. Rubin (University of
 California, Berkeley) using ZAP-cDNA synthesis kit

Art Unit: 1634

(Stratagene) and Superscript II RT (Life Technologies)."

ORIGIN

Alignment Scores:

Pred. No.:	2.57e-115	Length:	826
Score:	1189.00	Matches:	221
Percent Similarity:	99.5%	Conservative:	0
Best Local Similarity:	99.5%	Mismatches:	1
Query Match:	97.9%	Indels:	1
DB:	2	Gaps:	0

US-10-538-001-174 (1-224) x BE791925 (1-826)

```

Qy      3  ProGlyArgTrpArgGlnHisLeuGlnProArgArgArgCysArgSerLeuProThrLeu 22
      |||
Db      5  CCAGGAAGGTGGCGTCAGCATCTGCAGCCGCGTCGACGTTGTCGGAGCCTCCCCACACTC 64

Qy     23  ProMetGluLysLeuAlaAlaSerThrGluProGlnGlyProArgProValLeuGlyArg 42
      |||
Db     65  CCCATGGAGAAGCTGGCGGCCTCTACAGAGCCCCAAGGGCCTCGGCCGCTCCTGGGCCGT 124

Qy     43  GluSerValGlnValProAspAspGlnAspPheArgSerPheArgSerGluCysGluAla 62
      |||
Db    125  GAGAGTGTCAGGTGCCGATGACCAAGACTTTCGCAGCTTCCGGTCAGAGTGTGAGGCT 184

Qy     63  GluValGlyTrpAsnLeuThrTyrSerArgAlaGlyValSerValTrpValGlnAlaVal 82
      |||
Db    185  GAGGTGGGCTGGAACCTGACCTATAGCAGGGCTGGGGTGTCTGTCTGGGTGCAGGCTGTG 244

Qy     83  GluMetAspArgThrLeuHisLysIleLysCysArgMetGluCysCysAspValProAla 102
      |||
Db    245  GAGATGGATCGGACGCTGCACAAGATCAAGTGCCGGATGGAGTGCTGTGATGTGCCAGCC 304

Qy    103  GluThrLeuTyrAspValLeuHisAspIleGluTyrArgLysLysTrpAspSerAsnVal 122
      |||
Db    305  GAGACACTCTACGACGCTCTACACGACATTGAGTACCGCAAGAAATGGGACAGCAACGTC 364

Qy    123  IleGluThrPheAspIleAlaArgLeuThrValAsnAlaAspValGlyTyrTyrSerTrp 142
      |||
Db    365  ATTGAGACTTTTGACATCGCCCGCTTGACAGTCAACGCTGACGTGGGCTATTACTCCTGG 424

Qy    143  ArgCysProLysProLeuLysAsnArgAspValIleThrLeuArgSerTrpLeuProMet 162
      |||
Db    425  AGGTGTCCCAAGCCCTGAAGAACCGTGATGTATCACCCTCCGCTCCTGGCTCCCCATG 484

Qy    163  GlyAlaAspTyrIleIleMetAsnTyrSerValLysHisProLysTyrProProArgLys 182
      |||
Db    485  GGCGCTGATTACATCATTATGAATACTCAGTCAAACATCCCAAATACCCACCTCGGAAA 544

Qy    183  AspLeuValArgAlaValSerIleGlnThrGlyTyrLeuIleGlnSerThrGlyProLys 202
      |||
Db    545  GACTTGGTCCGAGCTGTGTCCATCCAGACGGGCTACCTCATCCAGAGCACAGGGCCCAAG 604

Qy    203  SerCysValIleThrTyrLeuGlyProGlyGlyProGlnArgLeuLeuThrGlnValGly 222
      |||
Db    605  AGCTGCGTCATCACCTACCT-GGCCCAGGTGGACCCAAAGGCTCCTTACCAAGTGGGT 663

Qy    223  GlyGlu 224
      |||
Db    664  GGTGAA 669

```

Any inquiry concerning this communication or earlier communications from the examiner should be directed to James Martinell whose telephone number is (571) 272-0719.

Art Unit: 1634

The examiner works a flexible schedule and can be reached by phone and voice mail.

Alternatively, a request for a return telephone call may be e-mailed to james.martinell@uspto.gov. Since e-mail communications may not be secure, it is suggested that information in such requests be limited to name, phone number, and the best time to return the call.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla, can be reached on (571) 272-0735.

OFFICIAL FAX NUMBER

The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300. Any Official Communication to the USPTO should be faxed to this number.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.


James Martinell, Ph.D.
Primary Examiner
Art Unit 1634

12/17/07